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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,940	01/21/2005	Masahiro Takeuchi	Q85885	8998

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EXAMINER	
SALMON, KATHERINE D	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 10/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/521,940	TAKEUCHI ET AL.	
	Examiner	Art Unit	
	Katherine Salmon	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) *1,2,6 and 8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-5,7 and 9* is/are rejected.

7)☒ Claim(s) *3-5,7 and 9* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *1/21/2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/05/06, 1/21/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II, Claims 3-5, 7, and 9 and SEQ ID No. 4 and 3 in the reply filed on 7/07/2006 is acknowledged.

The reply traverses the requirement for rejection. The reply asserts that the GenBank sequence used to show that the inventions are not so linked as to form a single general inventive concept under PCT rule 13.1 was not provided in the requirement for restriction (p. 2 1st paragraph). The reply asserts MPEP 803.04 states that normally ten sequences constitute a reasonable number and therefore the eleven sequences recited in the claims would not be a burden because it is only one more than what is recognized as normally reasonable by the MPEP (p. 3 3rd – 5th paragraphs). These arguments have been thoroughly considered but have not been found persuasive.

The GenBank sequence is being provided with the instant action so that the applicants are provided a copy of the reference used in the requirement for restriction. Further, MPEP 803.04 states "Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction". "Up to ten" sequences would include one sequence. The requirement for restriction of sequences was made because it is a burden for the office to search more than one patentably distinct sequence and therefore the restriction was made based on the MPEP 803.04 statement of "up to ten".

2. Claims 1-2, 6, and 8 are withdrawn from consideration.

3. An action on the merits fro Claims 3-5, 7, and 9 is presented below.

Priority

4. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a translation of the foreign application should be submitted under 37 CFR 1.55 in reply to this action.

Information Disclosure Statement

5. The information disclosure statements (IDS) submitted on 1/21/2005 and 7/06/2006 have been considered. It is noted that ONLY the abstracts have been provided for the foreign patent documents listed on IDS 1/21/2005, therefore, the foreign patent documents have only been considered with regard to the Abstracts.

Claim Objections

6. Claims 3-5 and 9 are objected to because of the following informalities: Claim 3 needs to be amended to include the limitations of Claim 1 and 2 because Claim 1 and 2 are withdrawn. Appropriate correction is required.

Claim Rejections - 35 USC § 112- Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 3-5, 7, and 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). *Wands* states at page 1404,

> "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The nature of the invention and breadth of claims

Claim 3 is drawn to a polynucleotide encoding a polypeptide comprising an amino acid sequence represented by SEQ ID No. 4. Claim 4 is drawn to an expression vector. Claim 5 is drawn to a cell transformed with the expression vector. Claim 7 is drawn to a polynucleotide, which specifically hybridizes to a polynucleotide represented

by SEQ ID No. 3 and has at least 15 nucleotides. Claim 9 is drawn to a kit comprising forward and reverse primers designed for enabling specific amplification of a gene represented by the polynucleotide of Claim 3.

The claims are drawn to ANY number of potential fragments of SEQ ID No. 3 and 4. The claims do not describe the number or identity of nucleotides flanking the recited nucleic acid fragments. The claims encompass nucleic acids, which comprise any nucleic acid variant of any size fragments of Seq ID No. 3 and 4. The claims encompass variants, which include nucleotide substitutions, additions, deletions, translocation, and truncations.

The invention is in a class of invention, which the CAFC has characterized as "the unpredictable arts such as chemistry and biology." Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 1330 (Fed. Cir. 2001).

Guidance in the Specification

The specification asserts RA3 (SEQ ID No. 3 and 4) is a polypeptide unknown in the art (p. 11 last paragraph). The specification asserts elevation of the Rheumatoid Arthritis (RA) expression level according to the severity of the inflammatory symptoms of RA was found (p. 11-12 last paragraph and 1st paragraph respectively).

The specification asserts 6 full-length gene sequences were derived using cDNA from the human spleen (p. 7 1st paragraph). The specification asserts expression of proteins encoded by the 6 genes in animal cell strains (p. 7 1st paragraph). The

specification asserts expression levels of the 6 genes were elevated in the synovial tissues of human RA patients (p. 7 1st paragraph). The specification asserts that the severity of the inflammatory symptoms of RA is related with the elevation of the expression level of the genes (p. 7 1st paragraph). The specification does not describe the 6 genes by anything other than SEQ ID. It is unclear if these are full genes because none of the defining features of a gene has been pointed out. There is no description of intron or exon regions of the genes and only the mRNA sequence has been provided. Further the claims are drawn to ANY amino acid fragment of SEQ ID NO. 4 and ANY nucleotide sequence, which will hybridize to SEQ ID No. 3.

The specification does not describe any fragments of the SEQ ID No. 3 or 4. The genus of the claims includes numerous fragments, homologs, and mutations of SEQ ID No. 3 and 4, yet the specification only teaches the sequences of SEQ ID 3 and 4.

The claims as broadly written encompass a significantly large genus of nucleic acids defined only in terms of fragments of SEQ ID No. 3 and 4 and not defined in terms of the flanking nucleotides or the functional activity of the nucleic acid. The specification does not teach a representative number of variants within this broadly claimed genus of nucleic acids. It would be unpredictable that ANY fragments could be could be determined as having an "enhanced expression in chronic rheumatoid arthritis patients" because the claims are drawn to any number of possible fragments with any number of possible flanking nucleotides.

Working Examples

The specification asserts the cloning of full-length open reading frame and construction of plasmid expression protein (p. 35 Example 1). The specification assets using primers, human spleen-derived cDNA and PCR the sequences were amplified so that the ORF of 101 amino acids was produced (p. 36-37).

The specification asserts synovial tissue and cells were recovered from human RA and human OA patients (p. 39 Example 3).

The specification asserts R1 and R2 are synovial fibroblast-like cell samples from two human RA patients (p. 40 1st full paragraph). The specification asserts RS1 has a larger inflammation level than that of RS2 (p. 40 1st full paragraph). It is unclear if RS1 is identical to R1 and RS2 is identical to R2.

The specification asserts an elevated expression level in RA3 in RS1 and RS2 (Table 3 p. 46). The specification asserts Figure 2 shows the expression level of the individual gene in RA synovial fibroblast-like cells in comparison with OA fibroblast-like cells. It is unclear that the elevated expression of RA3 is correlated with, and further, it is unclear if this correlation can be observed with ANY fragment of RA3 as claimed. The correlation is with RA synovial fibroblast cells and it is unclear if an expression level change can be associated with ANY individual in ANY type of cell.

The specification provides only 2 samples, which show an elevated expression level of RA3 compared to 1 OA sample. It is unpredictable that a correlation in 2 patients will be observed in ANY RA patient. Further, it is unclear if ANY fragment would produce the same expression levels. The specification fails to provide a p-value

or a "normal control" therefore it is unclear if expression levels are actually "elevated" in RA patients or merely decreased in OA patients.

The unpredictability of the art and the state of the prior art

The art teaches that though arthritis does have genetic factors, the association between those factors and arthritis is not always clear. Seldin et al. (Arthritis and Rheumatism 1999 Vol. 42 p. 1071) teaches that disease prevalence is assessed with large population-based studies (p. 1072 1st column last paragraph). Seldin et al. teaches positive associations are observed when there are 1) inadequate matching between controls and the disease group (population stratification, 2) direct involvement of the allele in disease pathogenesis, and 3) involvement of genes in linkage disequilibrium with test allele (p. 1073 2nd column 2nd paragraph). Therefore, the art teaches that associations of genes with expression in disease patients needs large, uniform population studies.

The art teaches numerous sequences which are composed of fragments of SEQ ID No. 3 and SEQ ID No. 4 that are not associated with arthritis, and further, are from a diverse genus of both plant and animal species. For example, BF974240 (NCBI GenBank January 22, 2001) shows a polynucleotide sequence which 96.1% identical to the SEQ ID No. 3. Nucleotides 1-114 of BF974240 are identical to nucleotides 213-326 of the instant application. Nucleotides 116-306 of BF974240 are identical to nucleotides 328-517 of the instant application. For example, BQ061938 (NCBI GenBank April 2, 2002) shows a polynucleotide sequence which 100% identical to the SEQ ID No. 3.

Nucleotides 203-508 of BQ061938 are identical to nucleotides 1-306 of the instant application. Both of these sequences are from a human lymphoma cell line. It is unpredictable that ANY fragment of a sequence would be correlative to RA. The specification has failed to prove a satisfactory number of fragments of SEQ ID 3 and 4 to enable the large genus of fragments encompassed by the claims.

Quantity of Experimentation

The quantity of experimentation in this area would be extremely large since there is significant number of parameters that would have to be studied. To practice the invention as broadly as it is claimed, the skilled artisan would have to determine every possible fragment of SEQ ID No. 3 and 4. The skilled artisan would have to determine nucleic acid molecules with any number of substitution, deletions, or insertions.

The skilled artisan would need to perform undue experimentation to correlate ANY fragment with detection of RA. The unskilled artisan would need to perform undue experimentation to perform a large uniform population study with normal controls with every possible fragment.

Despite knowledge in the art regarding how to mutate DNA molecules, generally, the specification fails to provide guidance as to where and what type of changes in the claimed sequence will result in the retention of expression of RA. Further, the specification only describes 1 species in a large genus of potential fragments.

The breadth of these claims is much larger than the scope enabled by the specification because the claims are drawn to fragments of any size and with any type and number of mutations whereas the specification only teaches a particular sequence.

Level of Skill in the Art

The level of skill in the art is deemed to be high.

Conclusion

Thus the applicants have not provided sufficient guidance to enable a skilled artisan to make the claimed invention in a manner reasonably correlated with the claimed ANY fragments of SEQ ID No. 3 and 4 and a kit for detecting RA. The skilled artisan would have to perform undue experimentation, which would require an extremely large amount of trial and error analysis in a large study to determine which fragments are associated with RA. There is still a significant amount of unpredictability in association ANY fragments with RA. The skilled artisan would have to determine every possible fragment in which the specification has provided no guidance of the potential flanking nucleotides around the fragment.

Thus given the broad claims in an art whose nature is identified as unpredictable, the unpredictability of that art, the large quantity of research required to define these unpredictable variables, the negative teachings in the art, and the lack of guidance provided in the specification balanced only against the high skill level in the art, it is the position of the examiner that it would require undue experimentation for one of skill in the art to produce the polynucleotides as broadly written in the claims.

Claim Rejections - 35 USC § 112-Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 3-5,7, and 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 3 is drawn to a polynucleotide encoding a polypeptide comprising an amino acid sequence represented by SEQ ID No. 4. Claim 4 is drawn to an expression vector. Claim 5 is drawn to a cell transformed with the expression vector. Claim 7 is drawn to a polynucleotide, which specifically hybridizes to a polynucleotide represented by SEQ ID No. 3, and has at least 15 nucleotides. Claim 9 is drawn to a kit comprising forward and reverse primers designed for enabling specific amplification of a gene represented by the polynucleotide of Claim 3.

When the claims are analyzed in light of the specification, the instant invention encompasses an enormous group of nucleic acid fragments. The specification does not describe which fragments are associated with detecting RA.

The claims as broadly written encompass isolated nucleic acids comprising any amino acid sequence of SEQ ID No. 4 and any nucleic acid sequence of SEQ ID No. 3 larger than 15 mer. It is noted that the 15 nucleotides of SEQ ID No. 3 are not limited to consecutive nucleotides. The specification does not provide an adequate written description of the claimed genus of nucleic acids as the claims are broadly written.

Additionally, the claims do not set forth the number or identity of nucleotides flanking the recited nucleic acid fragments. Accordingly, the claims encompass nucleic

acids which comprise the recited 15 mer fragments of SEQ ID NO: 3 or an amino acid of SEQ ID No. 4 but which share any overall level of sequence identity with SEQ ID NO: 3 or 4. The variants may include nucleotide substitutions, additions, deletions, translocations and truncations. The claims thereby encompass naturally and non-naturally occurring allelic, mutant and splice variants of SEQ ID No. 3 or 4.

The general knowledge in the art concerning homologues, mutants, allelic and splice variants does not provide any indication of how modification of the sequence of SEQ ID No. 3 or 4 will affect the functional properties of SEQ ID No. 3 or 4. The structure and function of one molecule does not provide guidance as to the structure and function of other molecules. Therefore, the description of one molecule (SEQ ID No. 3 or 4) is not representative of a genus of homologues, splice, mutant and allelic variants of SEQ ID No. 3 or 4 having unspecified functional activities different from that of SEQ ID No. 3 or 4. A general statement in the specification of a desire to obtain gene sequences, homologues from other species, mutated species, and polymorphic sequences is not equivalent to providing a clear and complete description of specific sequences which fall within the claimed genus of nucleic acids.

In analysis of the claims for compliance with the written description requirement of 35 U.S.C. 112, first paragraph, the written description guidelines note regarding genus/species situations that "Satisfactory disclosure of a ``representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register:

December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.) In the instant case, the specification fails to teach the necessary common attributes or features of the genus of encompassed nucleic acids in view of the species disclosed. As such, one of skill in the art would not recognize that applicant was in possession of the detection of ANY fragment of SEQ ID No. 3 or 4.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See page 1116).

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude, "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel* , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

The claims do not meet the written description provision of 35 USC 112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 3-5, 7, and 9 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Because of the use of open claim language and because the claims do not recite a purity or isolation limitations, the claims read on the nucleotide sequence as found in human. The native nucleotide sequence is a produce of nature and is not patentable.

This rejection may be overcomed by amendment of the claims to recite e.g. "an isolated and purified polynucleotide consisting of".

8. Claim 3-5, 7, and 9 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

The Claims are drawn to polynucleotides of an amino acid of SEQ ID No. 4 or fragments of at least 15 mer of SEQ ID No. 3.

The specification does not teach a specific utility for the invention. The specification asserts that the polynucleotide fragments of the invention can be used to detect

elevated levels of expression in RA patients. However, this assertion is not deemed to be substantial, as the specification does not teach a study in which the expression levels of RA patients are compared to a normal expression level. The specification asserts an elevated expression level in RA3 in RS1 and RS2 (Table 3 p. 46). The specification asserts Figure 2 shows the expression level of the individual gene in RA synovial fibroblast-like cells in comparison with OA fibroblast-like cells.

The specification provides only 2 samples, which show an elevated expression level of RA3 compared to 1 OA sample. The specification only teaches that in 2 patients expression levels were elevated when compared to an OA sample. From the teachings in the specification, it is evident that the expression levels of RA patients to normal controls was not known, therefore, rather the polynucleotide is associated with high expression levels is not know. Therefore, while the nucleotide sequence is found to be elevated in two patients compared to an OA patient, this is not considered a "real world" use for the claimed polynucleotides and kit. Further experimentation would be required to determine whether the elevated expression level is indicative of RA. Thus while the specification suggests that the nucleotides can be used to detect RA the specification does not demonstrate such.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claim 3, 7, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by BF974240 (NCBI GenBank January 22, 2001).

It is noted that the instant application SEQ ID No. 3 is the polynucleotide sequence of the amino acid sequence of the instant application SEQ ID No. 4. With regard to Claim 3, BF974240 shows a polynucleotide sequence which 96.1% identical to the SEQ ID No. 3. Nucleotides 1-114 of BF974240 are identical to nucleotides 213-326 of the instant application. Nucleotides 116-306 of BF974240 are identical to nucleotides 328-517 of the instant application.

The courts have stated that claims must be given their broadest reasonable interpretation consistent with the specification *in re Morris* , 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997); *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969); and *in re Zletz*, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) (see MPEP 2111). The claims are given the broadest reasonable interpretation consistent with the indefinite claim language and specification. The claim is drawn to a polynucleotide encoding a polypeptide comprising an amino acid sequence represented by SEQ ID No. 4. The claims are broadly read as a sequence, which encodes ANY fragment of SEQ ID No. 4.

With regard to Claim 7, BF974240 shows a polynucleotide sequence, which is at least 15 nucleotides similar to SEQ ID No. 3.

With regard to Claim 9, the kit is only contains fragments of the polynucleotide of Claim 3. BF974240 shows a sequence, which is encompassed by the limitations of Claim 3 and therefore provides all the named components needed in the kit.

10. Claims 3, 7, and 9 are rejected under 35 U.S.C. 102(a) as being anticipated by BQ061938 (NCBI GenBank April 2, 2002).

It is noted that the instant application SEQ ID No. 3 is the polynucleotide sequence of the amino acid sequence of the instant application SEQ ID No. 4. With regard to Claim 3, BQ061938 shows a polynucleotide sequence which 100% identical to the SEQ ID No. 3. Nucleotides 203-508 of BQ061938 are identical to nucleotides 1-306 of the instant application.

With regard to Claim 7, BQ061938 shows a polynucleotide sequence, which is at least 15 nucleotides similar to SEQ ID No. 3.

With regard to Claim 9, the kit is only contains fragments of the polynucleotide of Claim 3. BQ061938 shows a sequence which is encompassed by the limitations of Claim 3 and therefore provides all the named components needed in the kit.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over BF974240 (NCBI GenBank January 22, 2001) in view of Hawkins et al. (US Patent 6238666 May 29, 2001).

BF974240 shows a polynucleotide sequence which 96.1% identical to the SEQ ID No. 3. Nucleotides 1-114 of BF974240 are identical to nucleotides 213-326 of the instant application. Nucleotides 116-306 of BF974240 are identical to nucleotides 328-517 of the instant application.

BF974240, however, does not teach an expression vector comprising the polynucleotides or a cell transformed with the expression vector.

Hawkins et al. teaches nucleic acid sequences can be used in diagnostic assays to detect expression for autoimmune diseases (Column 4 lines 40-45). With regard to Claims 3 and 4, Hawkins et al. teaches the inclusion of polynucleotides in an expression vector which can be used to transform host cells (Column 4 lines 45-50).

Therefore, it would have been prima facie obvious to one of skill in the art at the time of the invention to incorporate the polynucleotide taught by BF974240 into an expression vector and incorporate a cell transformed with the vector as taught by Hawkins et al. The ordinary artisan would be motivated to produce the expression vector and cell as taught by Hawkins et al., because Hawkins et al. teaches expression vectors and host cells can be used to produce antisense molecules useful in diminishing or eliminating expression of genomic nucleotide sequence in individuals with overactive immune response (Column 4, lines 45-55).

13. Claims 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over BQ061938 (NCBI GenBank April 2, 2002) in view of Hawkins et al. (US Patent 6238666 May 29, 2001).

BQ061938 shows a polynucleotide sequence which 100% identical to the SEQ ID No. 3. Nucleotides 203-508 of BQ061938 are identical to nucleotides 1-306 of the instant application.

BQ061938, however, does not teach an expression vector comprising the polynucleotides or a cell transformed with the expression vector.

Hawkins et al. teaches nucleic acid sequences can be used in diagnostic assays to detect expression for autoimmune diseases (Column 4 lines 40-45). With regard to Claims 3 and 4, Hawkins et al. teaches the inclusion of polynucleotides in an expression vector which can be used to transform host cells (Column 4 lines 45-50).

Therefore, it would have been prima facie obvious to one of skill in the art at the time of the invention to incorporate the polynucleotide taught by BQ061938 into an expression vector and incorporate a cell transformed with the vector as taught by Hawkins et al. The ordinary artisan would be motivated to produce the expression vector and cell as taught by Hawkins et al., because Hawkins et al. teaches expression vectors and host cells can be used to produce antisense molecules useful in diminishing or eliminating expression of genomic nucleotide sequence in individuals with overactive immune response (Column 4, lines 45-55).

Conclusion

14. No Claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine Salmon whose telephone number is (571) 272-3316. The examiner can normally be reached on Monday-Friday 8AM-430PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Examiner
Art Unit 1634

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